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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,736	08/11/2005	Mara Brancaccio	4636-25	7505

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary	Application No.	Applicant(s)	
	10/538,736	BRANCACCIO ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25 and 40-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant filed a response to the Non-Final Rejection of May 3, 2006 on July 27, 2006. Upon further examination of the claims, the Examiner sets forth a new Restriction Requirement. The Restriction Requirement of January 11, 2006 was improperly executed by the previous examiner of record and contains multiple distinct inventions, for which a proper search and examination cannot be carried out.

As of Applicant's claims filed July 27, 2006, claims 26-39 are cancelled, claims 40-42 are new, and claims 12-14, 18, 19, 23, 24 are amended.

Claims 1-25, 40-42 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 2, 7-18, 40-42, drawn to a non-human transgenic animal comprising an increase in melusin expression levels and to a method of screening compounds for pharmacological activity using the non-human transgenic animal.

Group 2, claim(s) 1-18, 24, 25, 40-42, drawn to a non-human transgenic animal comprising a decrease in meulsin expression levels, to a method of screening compounds for pharmacological activity using the non-human transgenic animal, and to a method of making the non-human transgenic animal.

Group 3, claim(s) 19, drawn to method of studying a heart pathology using a non-human transgenic animal comprising an increase in melusin expression levels.

Group 4, claim(s) 19, drawn to method of studying a heart pathology using a non-human transgenic animal comprising a decrease in melusin expression levels.

Group 5, claim(s) 20,drawn to cells derivable from the non-human transgenic animal comprising an increase in melusin expression levels and to a method of screening compounds for pharmacological activity, using the cells.

Group 6, claim(s) 20-23,drawn to cells derivable from the non-human transgenic animal comprising an decrease in melusin expression levels and to a method of screening compounds for pharmacological activity, using the cells.

The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of Invention between different categories of inventions will only be found to exist if the specific combinations are present. These combinations include:

1) a product and special process of manufacture of said product,

2) a product and a process of use of said product,

3) a product, a special process of manufacture of said product, and a process of use of said product,

4) a process and an apparatus specially designed to carry out said process,

5) a product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

The groups do not share a special technical feature because the special technical feature, melusin, was known at the time of filing. For example, Brancaccio et al. 1999, JBC, 274: 29828-29288 teach that melusin was isolated in a two-hybrid screen and its pattern of expression in muscle was described in mouse embryos (Brancaccio et al., abstract and page 29284, 2nd col., 3rd parag. under "Regulation of Melusin Expression during Myogenic Differentiation").

Groups 1, 3, 5 are distinct from Groups 2, 4, 6 because an increase in melusin levels of a transgenic non-human animal is different from that of a decrease in melusin levels of a transgenic non-human animal. The search and examination of Groups 1, 3, 5 and 2, 4, 6 are burdensome because the searches are not coextensive.

Groups 1, 3, 5 are distinct from each other because while there is a relationship between Groups 1 and 3 as product and method of using the product, the product has other methods of use, such as in a screen for compounds. While there is a relationship between Groups 1 and 5, being the transgenic non-human animal and a cell obtained from the transgenic non-human animal, the Groups are distinct because the methods used in animals (in vivo) are different from those used on cultured cells (in vitro). While there is a relationship between Groups 3 and 5 in that the transgenic non-human animal is used in a study of heart pathology and that the animal is a source of cells, the study of Group 3 is *in vivo* and do not depend on the cultured cells of Group 5. The search and examination of each of the Groups is burdensome because the searches are not coextensive.

Groups 2, 4, 6 are distinct from each other because while there is a relationship between Groups 2 and 4 as product and method of using the product, the product has other methods of use, such as in a screen for compounds. While there is a relationship between Groups 2 and 6, being the transgenic non-human animal and a cell obtained from the transgenic non-human animal, the Groups are distinct because the methods used in animals (in vivo) are different from those used on cultured cells (in vitro). While there is a relationship between Groups 4 and 6 in that the transgenic non-human animal is used in a study of heart pathology and that the animal is a source of cells, the study of Group 4 is *in vivo* and do not depend on the cultured cells of Group 6. The search and examination of each of the Groups is burdensome because the searches are not coextensive.

The Groups are further restricted as follows.

Specifically named types of modification of melusin expression, stable or transient, as listed in claim 2, are distinct and one must be elected. The modifications are distinct because transient modification of melusin involves specific steps of gene induction and repression that are not used in systems that would express a gene stably. The search and examination of each modification of melusin expression is burdensome because the searches are not coextensive.

Should Applicant elect Group 2, 4, or 6, specifically named genetic approaches of homologous recombination, antisense RNA/DNA, and RNA/DNA interference of claim 5 are distinct and one must be elected. The genetic approaches are distinct because each has a distinct mode of function in reducing levels of melusin expression.

The search and examination of each genetic approach is burdensome because the searches are not coextensive.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Distinctly named species of melusin expression at levels of transcription, translation, or post-translation, as listed in claim 2, are distinct and one must be elected. The levels at which melusin are controlled are distinct because the methods of affecting transcription, translation, and post-translation require different method steps. The search and examination for all levels at which melusin expression is affected is burdensome because the searches are not coextensive.

Distinctly named species of methods of inducing a hypertensive condition, as listed in claims 8-10, are distinct species and one must be elected. The methods of inducing a hypertensive condition are distinct because each requires different method steps. The search and examination for each method is burdensome because the searches are not coextensive.

Distinctly named species of strains of mice, as listed in claim 17 are distinct species and one must be elected. The species of mice are distinct from each other because each has a different genetic background. The search and examination for each strain of mouse is burdensome because the searches are not coextensive.

Should Applicant elect Group 3 or 4, distinctly named heart pathologies, as listed in claim 19, are distinct and one must be elected. The heart pathologies are distinct from each other because each has a different etiology and pathology. The search and examination for each heart pathology are burdensome because the searches are not coextensive.

The following claim(s) are generic:

Claims 1, 2, 7-25, 40-42 of Groups 1-6 are generic for levels at which melusin expression are controlled.

Claims 1-7, 11-25, 40-42 of Groups 1-6 are generic for the methods of inducing a hypertensive condition.

Claims 1-25, 40-42 Groups 1-6 are generic for strains of mice.

Claim 19 of Group 3 is generic for heart pathologies.

Claim 19 of Group 4 is generic for heart pathologies.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER